JAN 18 2006

K053161

510(k) Summary for Sirona Dental Systems SIROLaser

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 32 94

Date Prepared: October 9, 2005

2. DEVICE NAME

Proprietary Name: SIROLaser
Common / usual name: Dental Soft Tissue Laser
Classification Names: Laser instrument, surgical, powered

3. PREDICATE DEVICE)

Ceralas D15

4. INTENDED USE

Intra- and extra-oral surgery including incision, excision, hemostasis, coagulation and vaporization of soft tissue.
Indications for use are the following applications: marginal and interdental gingiva and epithelial lining of free gingiva, frenectomy frenotomy, biopsy, operculectomy, Implant recovery, gingivectomy, gingivoplasty, gingival troughing crown lengthening, hemostasis of donor site removal of granulation tissue, laser assisted flap surgery debridement of deseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, removal of hyperplastic tissues, treatment of aphthous ulcers, leukoplakia, sulcular debridement (removal of

diseased or inflamed soft tissue, in the periodontal pocket), pulpotomy, pulpotomy as adjunct to root canal therapy.

5. Device Description

The SIROLaser is a Diode Laser System for dental soft tissue surgery. The system is comprised of the laser unit, laser fibers of different diameters hand pieces and tips of different angulations, a finger or a foot switch.

The SIROLaser has the following basic functions

- Ability to emit laser radiation either in continuous wave mode (cw) or chopped mode (laser radiation is switched on and off with a presetable frequency and a duty cycle of 1:1)
- Setup and display of treatment parameters:
  - power,
  - treatment time,
  - chop frequency
- Selection of predetermined settings for different indications
- Upgradeable firmware

6. Basis for Substantial Equivalence

The Sirona Dental Systems SIROLaser Device is substantially equivalent to the Ceramoptec Ceralas D15 (K983058, K991891) sold latterly under the Biolitec brand name SmilePro™ 980. Performance testing to validate the safety and effectiveness of the SIROLaser includes electrical safety, electromagnetic compatibility, and validation testing of both hardware and software functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2006

Sirona Dental Systems GmbH
c/o Mr. Stefan Preiss
TUV America, Inc.
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K053161
Trade/Device Name: SIROLaser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 30, 2005
Received: January 3, 2006

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

510(k) Number (if known): K053161

Device Name: SIROLaser

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Prescription Use __X __ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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